EXHIBIT C

Because products are used in different applications. You would have to test it in a similar circumstance to that application.

Q. Well, just make sure this is clear.

Do you know of any written standard adopted by the medical device industry for testing a medical device for oxidative degradation effects?

A. Well, you keep saying a "standard," and I would say that no such thing would exist. And that doesn't preclude a company from being responsible for testing for that effect.

Q. Okay. I notice in your report you talk about Ethicon's quality systems.

Do you recall that?

A. Yes, I do.

Q. And are there any written standards for quality systems for medical device manufacturers?

A. I understand that you want to use the term "standard."

There are guidelines and there are principles that are taught for quality systems. There are standards that have to do with risk analysis that would apply to medical devices, and that would affect some of the quality systems.

Q. Well --

A. What you are referring to would be something very specific that can't be applied across many different companies that are all operating in different ways.

But there are things outside of standards. There are engineering principles and there are guidelines provided. You just keep using the word "standards." And standards are not written for the quality systems, as -- as you've talked about, other than the ISO 14971 that has implications on quality.

Q. Okay. We'll get back to ISO 14971.

A. Uh-huh.

Q. I do have some questions about that.

But, aside from that written standard, do you know of any other written standards specific to the medical device manufacturing industry for quality systems, just specific to that industry?

A. I don't know that I've looked at -- specifically for a standard for quality systems for medical devices.

Q. So, when you express your opinions in this case regarding Ethicon's quality systems, what -- it sounds like you're just relying on some general principles that you go by in your

profession?

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. Let me -- let me strike that and ask it over.

Just please explain to me the standards or the guidelines that you applied in this case, the principles that you applied in this case in developing an opinion that Ethicon's quality systems were less than satisfactory.

A. Okay. The -- the -- the implication you've made is that, when we're designing or when you have quality systems, that all goes back to standards.

I teach all of the chemical engineering seniors at Vanderbilt University, and I teach a course called "Product and Process Design." It is not a course on standards. We have a full textbook of guidelines and principles. It is not built on standards. It's built on engineering fundamentals and principles that we follow in designing products and having quality systems.

And even courses that you take on quality and quality engineering are not based on standards. We teach engineering principles. And

to suggest that, if it's not in a standard, it's -- it's not scientific or it's not based on scientific principles, does not represent what standards are intended for.

Q. Okay. Have you ever heard of 21 CFR Part 820?

A. I don't know.

Q. Okay. I mean, you don't know what it is, do you?

A. Not from memory.

Q. Okay.

A. I know it's Code of Federal Regulations, and 21 represents the department that it would be associated with. I can't recall -- 19 is OSHA. I can't recall which particular division that is of the Code of Federal Regulations. I don't have that one memorized --

Q. Well --

A. -- whether I've seen it or not.

Q. I'm sorry. I apologize. I interrupted you.

Were you through?

A. Yes.

Q. Okay. Well, with respect to the Code of Federal Regulations, you mentioned OSHA.

the body?

A. I agree that I am qualified to tell you the effects of oxidative degradation on the polymer itself and how it changes the polymer properties. And I agree that Dr. Guelcher is the expert that I work with who can tell you the effect on the body.

Q. Well, I appreciate that. But I just have a very simple question. If you'll just answer it, I'll move on.

Will you agree that you personally are not qualified to evaluate the effects or potential effects of oxidative degradation of Prolene on the body, the human body?

A. I -- I will reiterate that I can -- I am qualified to talk about the changes in the polymer properties --

Q. That's not my question. I'm sorry to interrupt you, but. . .

A. I would defer that to Dr. Guelcher.

Q. So the answer to my question? Yes?

A. No, the answer to your question is to an extent.

Q. Well -- okay.

A. I know you think it's a simple question, but, if I don't think it's a simple

question, then we disagree.

Q. Do you know what fault class the potential failure mode of oxidative degradation of Prolene in the body would be?

A. The fault class --

Q. Yes.

A. -- is -- if I'm not mistaken, that is a specific term that -- classification that Ethicon has come up with.

Q. Well, what classification is it?

A. Doesn't matter to me. That's not part of the failure mode and effects analysis. Once you get the risk priority number, you don't have to put in a fault class. You've got severity, you've got occurrence, you've got detection.

If a company wants to further define it and put it in a fault class, that's something they're doing internally.

Q. What -- what is the severity ranking, in your view, for oxidative degradation as a failure mode in Prolene?

A. Okay. I'm going to back up one more step. And I'm going to tell you that, as I teach the students and the students work in groups and do failure mode and effects analysis, I can tell you

what my severity ranking -- you come up with that ranking collectively with expertise from a lot of different areas.

You're asking me to rank it just with my background and experience, and I'm telling you that's not how a safety analysis or a failure mode and effects analysis takes place.

In fact, if you look at the top of Ethicon documents, you'll see that it's a whole team that's in there and talking. So it would be a team that's sitting around that would say, how do we want to rank that severity? And we would have a discussion on what is that effect and what implications would it have.

I can tell you what happens to the polymer, and I would hope that a medical -- a medical device person or a medical doctor would say, oh, if the polymer gets hard and brittle, I see the harm as being the following.

Q. While I'm on that Exhibit 7, I noticed -- I'm just trying to make sure I understand all the documents you reviewed.

Look at the last page of Exhibit 7.

MR. BOWMAN: Is that the FMEA?

MR. DAVIS: Yes.

THE WITNESS: Yeah. I got it. I've got it here.

Yes?

BY MR. DAVIS:

Q. I just saw that list of documents.

Did you review all those documents?

A. I don't know.

Q. Well, I mean, did you -- well, okay, let me ask this about Exhibit 7: Did you sit down and read the entire dFMEA, Exhibit 7?

A. I believe I did.

Q. Well, the reason I ask, is I notice -- if you look at your report, you have a -- you have a table, Table 5.

Can you look at Table 5 in your report?

A. Yes.

Q. Is that an excerpt from Exhibit 7?

A. It is indeed.

Q. Okay.

A. And you will find the entire Exhibit 7 in my footnote --

Q. Okay.

A. -- notebook.

Q. Okay. Well, I mean, I've -- I've read some of your prior testimony where you've indicated

that you've gotten to where you can read these FMEAs and -- fairly quickly and go to the heart of what you're looking for.

Is that a fair assessment?

A. I believe I can, yes.

Q. Okay. What I'm trying to say, is that what you did in this case? Did you simply pick up Exhibit 7 and -- and search for all the references to mesh?

A. Well, it -- the spreadsheet was set up by Ethicon that you could search by component. Because the mesh component -- while I looked at the other components, while the mesh component is the component comprised of polypropylene and the component that I'm interested in, I looked at the other areas, but I very specifically looked at mesh.

Because, if you're going to consider oxidative degradation of the mesh, it wouldn't be listed on another component; it would be listed on mesh.

Q. And that's what I'm trying -- I'm just trying to understand. Was there any reason for you to read the entire dFMEA, Exhibit 7, or did you simply get on the native version and search for

mesh?

A. No. I -- okay. So I read the entire FMEA at least from a component standpoint in looking at the various components and whether or not that related to something I needed to look across the row at.

Q. Okay. Well -- and, again, I'm just trying to -- looking back at the last page of this.

As an example -- I'm trying to understand, like, did you ever -- did you read that page, for instance, in your work on this case?

A. Did I see this page? Yes, I saw this page.

Q. And did you read this page? Did it matter to you?

MR. BOWMAN: Object to form.

THE WITNESS: Did it matter to me?

BY MR. DAVIS:

Q. Did it have any significance to you?

MR. BOWMAN: Same objection.

THE WITNESS: I -- it had significance insofar as it states that it's documents referenced in the body of the FMEA.

BY MR. DAVIS:

Q. Okay. I'm -- I'm just trying to

understand, for instance, did you try to then go find or ask for all these documents, or not?

A. Not that I recall, because these were referenced in the FMEA, and what I was interested in was what was not included in the FMEA.

Q. Okay. Do you have any experience in developing quality systems for medical devices?

A. Well, the FMEAs -- that's a hard question for me to answer. I haven't -- I teach FMEAs, and I teach it to students who end up working in all kinds of areas. So -- I haven't applied it in a specific company, but I teach these concepts to students that go out and work for medical companies and. . .

Q. Have you ever taught about how to develop quality systems specifically for medical devices?

A. I teach generically how to do product and process design, and it's applied by chemical engineers to numerous industries. I don't teach about a specific industry.

Q. What -- what does "design controls" mean? I mean specifically for medical devices.

A. It would be parameters that you establish that you want to control those

characteristics.

Q. Okay. What -- what are the design controls generally accepted for medical devices?

A. It would be different for different medical devices.

Q. Can you -- can you just tell me what some of the design controls are for medical devices?

A. Oh. Well -- so, if I talked about the mesh component, because that's the component that I'm looking at for the medical device for the Prosima, certain design controls would be things like the weave, the diameter of the fiber, the density.

Q. That --

A. You're shaking your head no.

Q. Maybe we're on a different wavelength, because I'm asking you -- the process, the process of design controls, in designing and developing a medical device. Can you tell me what the design control processes are?

A. You're going to have to ask a -- I don't know what you're asking exactly.

Q. That's fair enough.

Do you have any experience in

maintaining a quality system for medical devices in particular?

A. It's no different for medical devices than other devices.

Q. So is the answer you don't have any specific experience for medical devices, or you do? Either you do or you don't.

A. I've never manufactured medical devices.

Q. So you've never had any experience in maintaining a quality system for medical devices; is that correct?

A. But I maintain that the quality systems I've been involved in in my work career are the same as those types of systems you'd put in place for medical devices.

Q. With that explanation, is the answer yes?

A. Ask the question again now.

Q. Have you ever had any experience in maintaining a quality system for a medical device in particular?

A. Not specifically for a medical device, but quality systems that I've maintained and been involved in in manufacturing operations are -- are

the same or very similar.

Q. Have you ever had any experience in auditing quality systems for medical devices?

A. Not specifically medical devices. Only other polymer-based products.

Q. And can you give me an overview of how you performed your audits?

A. Of other polymer products?

Q. Yes.

A. Sure. You -- you asked a question before that I guess I misinterpreted about design controls. So -- in auditing polymer-based products that I've been involved in and that we would manufacture, we had certain specifications or criteria, what I would call design controls. Certain parameters that you could measure that you were trying to target in the manufacturing process.

In -- in trying it maintain a quality system, you would go and pull random samples and test those versus your design controls.

Q. Okay.

A. If I'm understanding the question correctly.

Q. Now, do you have any experience in preparing any design controls for medical devices?

For the design and development of medical devices, that is.

A. Not specifically for medical devices; only for other polymer-based products.

Q. Okay. And what were those design controls?

A. For other polymer-based products?

Q. Yes.

A. They varied, depending on what the product was.

Q. Okay. I know it's your testimony, your opinion, that Ethicon's Prolene is subject to oxidative degradation.

I'd like to follow up on that and ask you, are there any degradation products of the oxidative degradation of Prolene?

A. Not typically. It -- the oxidative -- oxygen -- it -- it -- it depends on how it oxidizes. I need to be careful with that, because there's different oxidizing agents that can react with it. And, depending on the oxidizing agent that reacts with it, I think there can be some potential for byproducts.

In general, oxygen is attaching from some type of reactive oxygen species or even oxygen

from the air, and it breaks the chain, the long chain length of the polypropylene, into shorter chains.

Q. In that case, let's focus on Prolene in the body specifically.

A. Okay.

Q. Are there -- I know you've given the opinion that, in the body, there is oxidative degradation going on of the Prolene.

So I want to know, are there any degradation products resulting from the oxidation that -- degradation that you believe is occurring?

MR. BOWMAN: Object to form.

THE WITNESS: Can you point to in my report where I say that it's oxidizing in the body?

You said I said that it oxidized in the body. That's what -- there are reactive oxygen species in the body, but that specifically -- that oxidative mechanism inside the body is specifically what Dr. Guelcher reports on.

BY MR. DAVIS:

Q. Okay. You don't have an opinion as to whether Prolene oxidizes in the body --

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. -- is that correct?

A. No, that's not correct.

Q. Okay. Do you -- is it your opinion that Prolene, after implantation in the human body, is undergoing oxidative degradation?

MR. BOWMAN: Object to form.

THE WITNESS: Yes.

BY MR. DAVIS:

Q. Okay. And where is that in your report? I thought a minute ago you said -- you said it's not in your report.

A. It's not. I don't offer that as an opinion, and I'm not going to testify on that. But you asked if I believed that's happening. And, yes, I do believe that's happening.

Q. Okay.

A. But, the actual mechanism for how it's happening -- I say that because I've read Dr. Guelcher's report.

Q. Okay. But -- so -- my question then -- follow-up -- is, will you agree that it's not within your expertise to evaluate whether Ethicon's Prolene is undergoing oxidative degradation after implantation in the body?

MR. BOWMAN: Object to form.

THE WITNESS: Not the way that you worded that question, no, I don't agree with that.

BY MR. DAVIS:

Q. How did you -- how would you word it?

A. I'm not wording the question. I'm answering your question. So if you want to read it back, I'll answer it specifically.

Q. Okay. What expertise do you have to evaluate whether Ethicon's Prolene is undergoing oxidative degradation within the human body?

A. Okay.

MR. BOWMAN: Object to form.

THE WITNESS: I have expertise of what Prolene does outside the body and how it oxidizes. I have expertise on testing for oxidation.

BY MR. DAVIS:

Q. Outside the body, right?

A. Outside the body, or even something that was inside the body and then was taken out of the body. The testing is the same for that.

So I have expertise on testing even something that's come out of the body -- you asked if I had any expertise to see if it's oxidized in the body. You can take explants and you can do

testing and you can see if oxidation has occurred. And I have expertise in doing that and evaluating that.

Q. Have you done it in this case?

A. I do not have explants in this case, no.

Q. Okay. Do you know who the -- the name of the plaintiffs in this case are?

A. Jasso.

Q. Okay. Do you know anything about her?

A. I do not.

Q. Do you know what she had implanted in her?

A. I don't have any specific information about the plaintiff. I'm assuming it's a Prosima because that's what I was asked to evaluate for this case. But I was not asked to evaluate the effect in her body.

Q. Did you ask if any explants were available relating to Ms. Jasso?

By the way, I believe it's pronounced YAH-so.

A. Jasso.

Q. I may be wrong, but. . .

A. I don't recall if I asked that or not.

Q. Okay.

MR. LITZENBURG: I don't know if I can help to shortcut this at all, but Dr. Dunn will not be offered for any case-specific testimony --

MR. DAVIS: Okay.

MR. LITZENBURG: -- plaintiff specific.

MR. DAVIS: Thank you.

BY MR. DAVIS:

Q. Dr. Dunn, do you have any expertise on what occurs to Prolene within the body?

MR. BOWMAN: Object to form.

THE WITNESS: Yes.

BY MR. DAVIS:

Q. What is that expertise?

A. That, if it does oxidize, I know what the effect is on the polymer, the properties that it changes on the polymer, the molecular weight, the flexibility, that it goes from being ductile to being brittle, that it cracks, that it flakes.

Q. Well, but you started that with the word "if" it oxidizes, right?

A. Let's read back what your question was.

Can -- what was the last question I was asked?

(Whereupon the following question was

chemically in published literature, such as the fact that polypropylene has been known to oxidize for decades. So I agree.

Q. In fact, you -- in your own report, you -- you point out that polypropylene has been extensively studied since the 1960s, right?

A. Outside the body, yes.

Q. Okay.

Now, do you see where, at the bottom of page 3 of 6, the FDA goes on to explain that, in analyzing the need for biocompatibility testing, you should follow ISO 10993? Do you understand that?

A. Yes.

Q. And do you also --

A. Can -- I just want to point out one more time that biocompatibility and -- and chemical degradation were in different categories in the FMEA, and everything associated with biocompatibility that we're talking about was not in the category that I am discussing.

So continue on.

Q. Because you're saying that oxidative degradation is a chemical process, as opposed to -- as opposed to going to biocompatibility?